

REMARKS

Claims 1-21 and 26-28 are pending in this application and have been rejected in the Office Action. The claims have been amended as indicated above and support for the amendments can be found in paragraphs [0036] and [0038] of the original application.

Rejection under 35 U.S.C. § 102(b)

The Office has rejected claims 1-20 and 26 under 35 U.S.C. § 102(b) as being anticipated by Wilson et al. (U.S. Patent Application No. 2002/0099327) for the reasons noted on pages 2-4 of the Office Action. Applicant respectfully traverses this rejection.

1. Applicant respectfully traverses this rejection for the reasons of record, namely, that the Office has not shown that Wilson et al. describe a tunneler. Just because Wilson et al. describe a multi-lumen catheter that is “capable of being used as a tunneler” does not mean that the skilled artisan would understand that it is used as a tunneler. Indeed, the skilled artisan would understand that it is not used as a tunneler since Wilson et al. specifically disclose in several instances that the catheter 12 is pulled through a tunnel that has already been created. So something else, other than the catheter 12, has already created the tunnel and the catheter 12 is not being used as a tunneler.

Such a conclusion is supported by the attached Rule 132 Declaration. This Declaration, which was previously submitted but not considered by the Office, is signed by Kelly B. Powers, who is not an inventor of the present application and is not an employee of the Assignee of the present application. Mr. Powers reviewed Wilson et al. and came to the conclusion that in light

of its disclosure, and given his knowledge in the art, the skilled artisan would have concluded that the catheter 12 is not used as a tunneler. Mr. Powers also concluded that the skilled artisan would not have used the catheter 12 as a tunneler because it would have been difficult—if not impossible—for the catheter 12 to be pushed into the skin of a patient. Rather, it would have to be pulled through a patient, as it would in a tunneling procedure.

2. Some of the current claims recite that the tunneler (or tunneling system) contains a tunneler shaft for creating a tunnel in the skin of a patient where the shaft is made of rigid materials and containing a first end with a tapered section. The Office, however, has not substantiated that Wilson et al. anticipate such a claim limitation. Indeed, in light of its disclosure, it would unlikely that the Office could show that the device of Wilson et al. contains such features.

Thus, the Office has not shown that Wilson et al. teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 102(e)

The Office has rejected claims 26 under 35 U.S.C. § 102(e) as being anticipated by Wilson '396 (U.S. Patent No. 6921396) for the reasons noted on page 4 of the Office Action. Applicant respectfully traverses this rejection.

1. Claim 26 contains similar limitations as claim 1. Claim 26 also contains the limitation that the tunneler contains a tunneler shaft made of a rigid material. Applicant respectfully traverses the rejection over Wilson '396 for the same reason as Wilson et al.: namely, that the Office has not shown that Wilson '396 describe the claimed tunneler.

Wilson '396 describe a multi-lumen catheter 10 with a connector 12. *See Figure 1 and column 7, lines 28-30.* The connector 12 contains a coupling portion 24 that is configured to securely engage a corresponding coupling portion of a medical device such as a trocar, a syringe, or the like. *See column 8, lines 17-20.* Once the trocar 40 is connected to the catheter using the connector 12, the trocar 40 is used to guide the catheter 10 through the tunnel 106. *See column 8, lines 58-60.*

Thus, as with Wilson et al., the skilled artisan would understand that the catheter 10 is not used as a tunneler since Wilson '396 specifically disclose in several instances that the catheter 10 is pulled through a tunnel 106 using a trocar 40. In fact, most of column 2 of Wilson '396 discusses catheters and tunneling procedures and how a trocar acts as a tunneling device for catheters. Indeed, lines 41-42 of column 2 of Wilson '396 specifically describe that the trocar is part of the tunneling device. In light of such a disclosure, it is unlikely that the skilled artisan would have understood that the catheter 10 of Wilson '396 would either act as, or be used as, a tunneler.

2. Some of the current claims also recite that the tunneler (or tunneling system) contains a tunneler shaft for creating a tunnel in the skin of a patient where the shaft contains a first end with a tapered section. The Office, however, has not substantiated that Wilson '396 anticipates such a claim limitation. Indeed, in light of its disclosure, it would unlikely that the Office could show that the connector 12 of Wilson '396 (which the Office maintains is a tunneler shaft) contains such features since the skilled artisan would understand that the connector 12 is, as stated, merely a connector. The Office has pointed to no disclosure in Wilson '396 that would lead the skilled artisan to understand that this component (connector 12) could be used to create a tunnel.

Thus, the Office has not shown that Wilson '396 teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 102

The Office has rejected claim 21 under 35 U.S.C. § 102(e) as being anticipated by Zawacki et al. (U.S. Patent Application No. 2004/067463) for the reasons noted on page 4 of the Office Action. Applicant respectfully traverses this rejection.

1. The Office considers that Zawacki et al. describe a multi-lumen catheter (410) and a tunneler with a tip (430) containing multiple shaft members (440,450) with different lengths. But one with ordinary skill in the catheter art would have understood that the structure illustrated in Zawacki et al. as 410 is only a catheter that could not—and would not—have been used as a tunneler.

Zawacki et al. specifically disclose that the catheter 410 is pulled through a tunnel that has already been created in the desired location of the patient. Zawacki et al. describe that the shape of the venous lumen can be transitioned from a D-shape in the proximal portion to a circular shape in the distal portion. The cross-sectional area is configured for the venous lumen is also standardized to permit all sizes of the catheter to be tunneled subcutaneously during implantation using a single size of tunneling trocar. *See paragraph [0074] (emphasis added).*

In light of all of these disclosures, the skilled artisan would have concluded that a tunnel is created by a tunneler before a catheter 410 is inserted in the tunnel. Thus, the skilled artisan would have concluded that the catheter 410 is not used as a tunneler. In other words, the skilled

artisan would have understood that since a tunnel already exists when the catheter 410 is used, there would have been no reason to use the catheter 410 as a tunneler.

Such a conclusion is supported by the attached Rule 132 Declaration by Kelly B. Powers (who is not an inventor of the present application and is not an employee of the Assignee of the present application). But Mr. Powers is an inventor of Zawacki et al. Mr. Powers concludes that in light of the disclosure of Zawacki et al., and given the general knowledge known to one with ordinary skill in the art, the skilled artisan would have concluded that the catheter 410 is not used as a tunneler. Mr. Powers also concludes that the skilled artisan would not have used the catheter 410 as a tunneler because it would have been difficult—if not impossible—for the catheter 410 to be pushed into a patient. Rather, it would have to be pulled through a patient, as it would in a tunneling procedure.

2. Some of the current claims recite that the tunneler (or tunneling system) contains a tunneler shaft for creating a tunnel in the skin of a patient where the shaft is made of rigid materials and containing a first end with a tapered section. The Office, however, has not substantiated that Zawacki et al. anticipate such a claim limitation. Indeed, in light of its disclosure, it would unlikely that the Office could show that the device of Zawacki et al. contains such features.

Thus, the Office has not shown that Zawacki et al. teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 103

The Office has rejected claim 21 under 35 U.S.C. § 103 as being unpatentable over Imran (U.S. Patent No. 5964796) in view of Vardi et al. (WO 02/076333) for the reasons noted on pages 5-6. Applicant continues to traverse this rejection.

The Office alleges that Imran discloses “a gripping means 21.” *See Office Action at 4.* Applicants respectfully disagree. A review of Imran reveals that feature 21 is described by Imran as merely a body of an introducer sheath. *See column 3, lines 19-30.* Figure 2 illustrates feature 21, and based on that Figure, it is highly unlikely that the skilled artisan would consider feature 21 as a “gripping means.” The Office has pointed to no disclosure in Imran that would have led the skilled artisan to believe that body 21 contains a gripping means other than the mere allegation that tunneler 12 contains a gripping means (21). And the Office has not argued, much less alleged, that Vardi et al. describe such a limitation. And since the Office has not substantiated that either reference teaches this feature, it is unlikely that the Office can show that their combination teaches such a feature.

Nor it is likely that the skilled artisan would have modified Imran as proposed by the Office. The Office proposes to modify the device of Imran to have introducer shaft members with different lengths. But Imran teaches that his introducer contain tubular members 31 that are sized to contain two catheters 13. *See column 4, lines 41-49.* These two catheters 13 are designed to have the same mechanical characteristics. *See column 5, lines 53-54.* Thus, the skilled artisan would have concluded that the tubular members 31 containing these similar catheters 13 should likewise have similar characteristics. And since the tubular members 31 should be similar, the skilled artisan would have had no reason to follow the Office’s proposed modification of making them with different lengths. Indeed, there would have been no

motivation to follow the proposed modification and make tubular members 31 with different lengths since that teaches away from the disclosure of Imran.

Thus, neither Imran nor Vardi et al., either alone or in combination, disclose or suggest each and every element of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 103

The Office has rejected claims 27-28 under 35 U.S.C. § 103 as being unpatentable over Wilson '396 in view of Zawacki et al. for the reasons noted on page 6. Applicant respectfully traverses this rejection.

As noted above, the Office has not shown that either Wilson '396 or Zawacki et al. describe a tunneler, as recited in the claims. And since the Office has not substantiated that either cited reference teaches this feature, it is unlikely that the Office can show that their combination teaches such a feature.

Thus, neither Wilson et al. nor Zawacki et al., either alone or in combination, disclose or suggest each and every element of the claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Advisory Action

In the Advisory Action, the Office maintains the above rejections based on one main argument. The Office states that with regards to Applicant's arguments that a catheter would not

be used as a tunneler, this is a recitation of intended use of the claimed invention and if the prior art structure is capable of performing the intended use, then it meets the claims.

Applicants respectfully disagree with the Office's position from both a legal perspective and a technical perspective. From a legal perspective, the Office's arguments boil down to the position that the term "tunneler" (or tunneling system) is an intended use and, as such, holds no patentable weight. But the Office has incorrectly represented this legal doctrine.

While the term tunneler (and tunneling system) occurs in the body of some claims, it occurs in the preamble of most of the pending claims. But if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is "necessary to give life, meaning, and vitality" to the claim, then the claim preamble should be construed as if in the balance of the claim. *See M.P.E.P. § 2111.02; see also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Such is the case here where the term tunneler certainly gives life, meaning, and vitality to the claims.

There exist at least three instances when the preamble of a claim operates as a claim limitation. First, this occurs when a preamble term provides antecedent basis for a subsequent term in the claim, and when the preamble is essential to understand terms or limitations in the claim body. *See M.P.E.P. § 2111.02; see also Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002); *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). Such antecedent reference occurs several times in the current claims. Second, any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. *See M.P.E.P. § 2111.02; see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Such

terminology also exists in the current claims since the term tunneler limits the structure of the claimed device. Third, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. See *M.P.E.P.* § 2111.02; see also *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09. Applicant's reliance on the preamble language of tunneler to distinguish the claims throughout the prosecution would, if no other reason, dictate that this term must be treated as a claim limitation.

Thus, contrary to the Office's position, there exist numerous instances where the preamble must be given patentable weight. In fact, there are numerous instances similar to the present claims where the courts have decided that the preamble must be considered as a claim limitation. In *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951), the preamble recited "an abrasive article" for claims directed to an article comprising abrasive grains. That Court stated that it is only by this phrase that it can be known that the subject matter defined by the claims is an abrasive article. In *Poly-America LP v. GSE Lining Tech. Inc.*, 383 F.3d 1303, 1310, 72 USPQ2d 1685, 1689 (Fed .Cir. 2004), the Federal Circuit stated that the preamble language relating to "blown-film" does not state a purpose or an intended use, but rather discloses a fundamental characteristic of the claims that is properly construed as a limitation of the claim.

Perhaps the closest factual situation to the present application can be found in the decision of *In re Reichel*. In this decision, the preamble of the claims recited an expandable diaphragm device. The cited prior art devices were all directed to a metallic container that could not achieve the expandable feature. The court noted that while the claimed invention had a

structure similar to the prior art, the prior art reference was avoided expansion and contraction as far as possible and could not anticipate the claimed invention. *In re Reichel*, 84 F.2d 221, 223 (CCPA 1936). And so it is in the present application. Some of the claims in the present application recited a tunneler in the preamble. The cited prior art (Wilson et al., Wilson '396, and Zawacki et al.) relate to a catheter that could not be used as a tunneler. So even if the Office could show that this cited prior art had a similar structure, the Office can't cite this prior art as anticipating the current claims.

Separate from these legal reasons, the Office's position fails from a technical perspective. The Office has argued that if the prior art structure is capable of performing the intended use, then it meets the claim. The problem is that the Office has not shown that the prior art structure (of a catheter) is capable of acting as a tunneler. Applicant has repeatedly pointed to disclosures in the prior art where something other than the catheter (i.e., a trocar) is used to create the tunnel of where the tunnel already exists by the time the catheter is used. Thus, the skilled artisan would understand that the prior art structures are actually not capable of acting as a tunneler. Such a technical conclusion is supported by the Declaration of Mr. Powers.

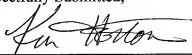
CONCLUSION

For the above reasons, as well as those of record, Applicant respectfully requests consideration of the Rule 132 Declaration and withdrawal of the pending grounds of rejection.

If there is any fee due in connection with the filing of this Amendment, including a fee for any extension of time not accounted for above, please charge the fee to our Deposit Account No. 50-0843.

Respectfully Submitted,

By



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Date: April 1, 2008